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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,491	07/01/2003	Vahid Saadat	USGINZ02112	3557
40518 7590 05/26/2009 LEVINE BAGADE HAN LLP 2400 GENG ROAD, SUITE 120 PALO ALTO, CA 94303				
EXAMINER				
YABUT, DIANE D				
ART UNIT		PAPER NUMBER		
3734				
MAIL DATE		DELIVERY MODE		
05/26/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/612,491

Applicant(s)

SAADAT ET AL.

Examiner

DIANE YABUT

Art Unit

3734

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 16, 26, 27 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 16, 26, 27 and 32-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. In view of the appeal brief filed on 02/02/2009, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites the limitation "the tissue fold" in the last line. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(c) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 39-40 are rejected under 35 U.S.C. 102(c) as being anticipated by **Adams et al.** (U.S. Patent No. **6,736,828**).

Adams et al. disclose moving a catheter **16** into a patient, holding a tissue fold **14** within the patient with a tissue grasper **18**, extending a piercing element **40** from the catheter through the tissue fold, moving a first anchor (one end of element **42**) out from the piercing element on a first side **46** of the tissue fold, withdrawing the piercing element from the tissue fold, moving a second anchor (the other end of element **42**) out from the piercing element on a second side **44** of the tissue fold, and holding the tissue fold via a connection element **42** connecting the first and second anchors (Figures 1 and 5-7).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 5-7, 9, 16, 26, and 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Patent No. **6,736,828**) in view of **Saadat** (U.S. Patent No. **7,186,262**).

Adams et al. disclose providing a delivery catheter or endoscope **16** having a needle **40** translatably disposed therein, a distal end, a stabilization device **18** disposed at the distal end

holding a tissue fold **14**, one or more anchors (either end of element **42**) disposed within the needle, advancing the delivery catheter into the gastroesophageal junction, engaging the stabilization device to a tissue wall of the gastroesophageal junction, advancing the needle through the catheter and a first tissue wall **46** and a second tissue wall **44**, ejecting anchors (ends of element **42**) from a distal tip of the needle, the anchors having a suture or connection element **42** attached thereto, withdrawing the needle from the tissue walls whereby the suture is extended through the tissue walls and the first and second anchors are placed on either side of the tissue walls to maintain the tissue fold (see abstract, Figures 1 and 5-7).

Although a gastroesophageal junction is accessed instead of tissue walls of a gastrointestinal lumen to create a tissue fold, it would have been obvious to one of ordinary skill in the art to apply the fundoplication method of Adams et al. to gastrointestinal tissue since it was well known in the art to manipulate gastric tissue by fundoplication to reduce the area of a gastrointestinal lumen for aiding obese patients in managing the amount of food desired and eaten.

Adams et al. also lacks translation of a fastener over the suture whereby a tension force is created on the suture and the tissue fold is maintained, wherein the fastener has collar through which the suture extends.

Saadat teaches translating a fastener **532** comprising a collar with a central channel through which a suture **506** extends whereby a tension force is created on the suture and said tissue fold is maintained (Figure 49A; col. 24, lines 42-51). It would have been obvious to one of ordinary skill in the art to modify Adams et al. by replacing the anchors and connecting

element **42** with a suture fastener or crimp with a channel, as taught by Saadat, so that the tension is maintained and the fastener may be translated over the suture after the tissue has been approximated to adjust tension.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Patent No. **6,736,828**) in view of **Saadat** (U.S. Patent No. **7,186,262**), as applied to claim 1 above, and further in view of **Koike et al.** (U.S. Patent No. **6,056,760**).

Adams et al. and Saadat disclose the claimed invention except for ejecting the anchor from the distal tip of the needle by translating a push rod disposed in the needle.

Koike et al. teach ejecting an anchor from a distal tip of the needle comprising translating a push rod **3** disposed in the needle (Figures 1 and 7 and col. 4, lines 58-67). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a push rod to eject the anchors, as taught by Koike et al., to Adams et al. and Saadat to facilitate advancement and positioning of the anchors.

9. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Patent No. **6,736,828**) in view of **Saadat** (U.S. Patent No. **7,186,262**), as applied to claim 1 above, and further in view of **Laufer et al.** (U.S. Pub. No. **2004/0194790**).

Adams et al. and Saadat disclose the claimed invention except for the stabilization device being a coil with a sharpened tip and rotating the coil to engage the coil into the tissue wall.

Laufer et al. teach a stabilization device **740** disposed at the distal end comprising a coil **740**, or tissue holding element, having a sharpened tip and engaging the stabilization device to

the tissue wall by rotating the coil (Figure 4A and page 3, paragraphs 79 and 83). It would have been obvious to one of ordinary skill in the art to provide a rotating coil stabilization device, as taught by Laufer et al., to Adams et al. and Saadat to facilitate engagement with tissue as the coil is biased in a distal direction to urge against tissue (page 1, paragraph 7).

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Adams et al.** (U.S. Patent No. **6,736,828**) in view of **Saadat** (U.S. Patent No. **7,186,262**), as applied to claim 26 above, and further in view of **Gannoe et al.** (U.S. Patent No. **6,746,460**).

Adams et al. and Saadat disclose the claimed invention, including creating a tissue fold, except for creating a second tissue fold on an opposing tissue wall.

Gannoe et al. teach providing creating a second tissue fold on an opposing tissue wall (Figure 5A and col. 5, lines 23-37). It would have been obvious to one of ordinary skill in the art to provide a second tissue fold, as taught by Gannoe et al., to Adams et al. and Saadat since providing a multitude of folds depends on the desired results and the anchoring configuration or to facilitate further approximation of multiple sections tissue.

Response to Arguments

11. Applicant's arguments with respect to claims 1-7, 9, 16, 26-27, and 32-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734